IN THE CLAIMS

I. Cancellation of Claims

Please cancel claims 22-26, 28-52, 56, 59, and 65-78, without prejudice or disclaimer.

II. Substitution of Claims

Please substitute pending claims 1-5, 27, 53-55, 57, 58, 60-64, and 79, with the corresponding amended claims, as shown below:

1. (Amended) A method of transdermally delivering testosterone to a male subject in need thereof, comprising administering to the subject a pharmacologically effective amount of a composition to a selected area of skin of the subject, wherein the composition comprises:

a) about 0.1 % to about 10 % testosterone;

b) about 30 % to about 98 % alcohol selected from the group consisting of ethanol, and isopropanol;

c) about 0.1 % to about 5 % isopropyl myristate;

d) about 1 % to about 5 % sodium hydroxide; and

e) about 0.1 % to about 5 % gelling agent; and

wherein the percentages are weight to weight of the composition, and the testosterone is absorbed into bloodstream of the subject at a rate and duration that maintains a circulating serum concentration of the testosterone greater than about 400 ng testosterone per dl serum during a time period beginning about 2 hours after administration and ending about 24 hours after administration.

2. (Amended) The method of claim 1, wherein the composition is administered daily for at least about 7 days.

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3. (Amended) The method of claim 1, wherein the composition is administered daily for at least about 30 days.

4. (Amended) The method of claim 1, wherein the composition is administered daily for at least about 180 days.

5. (Amended) The method of claim 1, wherein the administration of the composition exhibits dose proportionality.

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27. (Amended) The method of claim 1, wherein the testosterone comprises an enantiomer, a racemic mixture, a derivative, a base, or a salt thereof.

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53. (Amended) The method of claim 1, wherein the composition administered weighs about 1.0 gram to about 10 grams.

54. (Amended) The method of claim 1, wherein the composition administered weighs about 2.5 grams to about 7.5 grams.

55. (Amended) The method of claim 1, wherein the composition administered weighs about 2.5 grams to about 5.0 grams.

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57. (Amended) The method of claim 1, wherein the composition comprises about 0.5 % to about 5 % testosterone.

58. (Amended) The method of claim 1, wherein the composition comprises about 1 % testosterone.

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60. (Amended) The method of claim 1, wherein the composition comprises about 0.25 % to about 2.5 % isopropyl myristate.

61. (Amended) The method of claim 1, wherein the composition comprises about 0.5 % isopropyl myristate.

62. (Amended) The method of claim 1, wherein the gelling agent is polyacrylic acid.

63. (Amended) The method of claim 62, wherein the composition comprises about 0.9 % polyacrylic acid.

64. (Amended) The method of claim 1, wherein the composition comprises about 40 % to about 90 % alcohol.

79. (Amended) The method of claim 86, wherein the packet comprises a polyethylene liner between the composition and inner surface of the packet.

II. Addition of Claims

Please add the following claims:

80. (New) The method of claim 1, wherein the serum testosterone concentration is maintained between about 400 ng testosterone per dl serum to about 1050 ng testosterone per dl serum.

81. (New) The method of claim 1, wherein for each about 0.1 gram per day administration of the composition to the skin, an increase of at least about 5 ng/dl in serum testosterone concentration results in the subject.

82. (New) The method of claim 1, wherein the composition is provided to the subject for daily administration in a dose of approximately 0.1 g, 2.5 g, 5 g, 7.5 g, or 10 g.

83. (New) The method of claim 82, wherein the dose is approximately a 5 g dose delivering about 50 mg to about 100 mg of testosterone to the skin.

84. (New) The method of claim 82, wherein the dose is approximately a 7.5 mg dose delivering about 50 mg to about 100 mg of testosterone to the skin.

85. (New) The method of claim 82, wherein the dose is approximately a 10 g dose delivering 50 mg to about 100 mg of testosterone to the skin.

86. (New) The method of claim 82, wherein the composition is provided to the subject in one or more packets.

87. (New) The method of claim 1, wherein maximum serum testosterone concentration in the subject is reached about 16 hours after administration of the composition on day one of administration.

88. (New) The method of claim 1, wherein after at least about 30 days of daily administration serum testosterone concentration in the subject is at least about 490 ng/dl to about 860 ng/dl.

89. (New) The method of claim 1, wherein after at least about 30 days of daily administration serum dihydrotestosterone concentration in the subject is greater than about 54 ng/dl.

90. (New) The method of claim 1, wherein after at least about 30 days of daily administration a ratio of serum dihydrotestosterone concentration to serum testosterone concentration of greater than about 0.23 is achieved in the subject.

91. (New) The method of claim 1, wherein after at least about 30 days of daily administration total serum androgen concentration in the subject is greater than about 372 ng/dl.

92. (New) The method of claim 1, wherein after at least about 30 days of daily administration serum estradiol concentration in the subject is greater than about 28 pg/ml.

93. (New) The method of claim 1, wherein the subject has primary hypogonadism prior to administration.

94. (New) The method of claim 93, wherein after at least about 30 days of daily administration serum follicle stimulating hormone concentration in the subject is less than about 11 mIU/ml.

95. (New) The method of claim 1, wherein the subject has secondary hypogonadism prior to administration.

96. (New) The method of claim 95, wherein after at least about 30 days of daily administration serum follicle stimulating hormone concentration in the subject is less than about 3.7 mIU/ml.

97 (New) The method of claim 1, wherein the subject has a pretreatment serum follicle stimulating hormone concentration greater than a normal range of a normal subject.

98. (New) The method of claim 97, wherein after at least about 30 days of daily administration the serum follicle stimulating hormone concentration is within or below the normal range.

99. (New) The method of claim 1, wherein the subject has a pretreatment serum luteinizing hormone concentration greater than a normal range of a subject having primary hypogonadism.

100. (New) The method of claim 99, wherein after at least about 30 days of daily administration serum luteinizing hormone concentration is within the normal range.

101. (New) The method of claim 101, wherein after at least about 30 days of daily administration the serum luteinizing hormone concentration is less than about 6.8 mIU/ml.

102. (New) The method of claim 1, wherein after at least about 30 days of daily administration the testosterone has an accumulation ratio in the male subject greater than about 1.5.

103. (New) The method of claim 1, wherein after at least about 30 days of daily administration the testosterone has a net AUC_{0-24} in the male subject greater than 220 nmol*h/l.

104. (New) A method of transdermally delivering testosterone to a male subject in need thereof, comprising:

(a) preparing a composition which comprises

1) about 0.1 % to about 10 % testosterone;

2) about 30 % to about 98 % alcohol selected from the group consisting of ethanol, and isopropanol;

3) about 0.1 % to about 5 % isopropyl myristate;

4) about 1 % to about 5 % sodium hydroxide; and

5) about 0.1 % to about 5 % gelling agent; and

(b) applying the composition to a selected area of skin of the subject in an amount effective to treat hypogonadism in the subject;

wherein the percentages are weight to weight of the composition.

105. (New) The method of claim 104, wherein the composition is applied for at least about 7 days.

106. (New) The method of claim 104, wherein the composition is applied for at least about 30 days.

107 (New) The method of claim 104, wherein the composition is applied for at least about 180 days.

108. (New) The method of claim 104, wherein the application of the composition exhibits dose proportionality.

109. (New) The method of claim 104, wherein the testosterone comprises an enantiomer, a racemic mixture, a derivative, a base, or a salt thereof.

110. (New) The method of claim 104, wherein the composition applied weighs about 1 gram to about 10 grams.

111. (New) The method of claim 104, wherein the composition applied weighs about 2.5 grams to about 7.5 grams.

112. (New) The method of claim 104, wherein the composition applied weighs about 2.5 grams to about 5 grams.

113. (New) The method of claim 104, wherein the composition comprises about 0.5 % to about 5 % testosterone.

114. (New) The method of claim 104, wherein the composition comprises about 1% testosterone.

115. (New) The method of claim 104, wherein the composition comprises about 0.25% to about 2.5 % isopropyl myristate.

116. (New) The method of claim 104, wherein the composition comprises about 0.5% isopropyl myristate.

117. (New) The method of claim 104, wherein the gelling agent is polyacrylic acid.

118. (New) The method of claim 117, wherein the composition comprises about 0.9 % polyacrylic acid.

119. (New) The method of claim 104, wherein the composition comprises about 40% to about 90% alcohol.

120. (New) The method of claim 104, wherein the testosterone is absorbed into the bloodstream of the subject at a rate and duration that maintains a circulating serum concentration of the testosterone greater than about 400 ng testosterone per dl serum during a time period beginning about 2 hours after application and ending about 24 hours after application.

121. (New) The method of claim 104, wherein the serum testosterone concentration is maintained between about 400 ng testosterone per dl serum to about 1050 ng testosterone per dl serum during a time period beginning about 2 hours after application and ending about 24 hours after application.

122. (New) The method of claim 104, wherein for each about 0.1g/day application of the composition to the skin, an increase of at least about 5 ng/dl in serum testosterone concentration results in the subject.

123. (New) The method of claim 104, wherein the composition is provided to the subject for daily application in a dose of approximately 0.1 g, 2.5 g, 5 g, 7.5 g, or 10 g.

124. (New) The method of claim 123, wherein the dose is approximately a 5 g dose delivering about 50 mg to about 100 mg of testosterone to the skin.

125. (New) The method of claim 123, wherein the dose is approximately a 7.5 mg dose delivering about 50 mg to about 100 mg of testosterone to the skin.

126. (New) The method of claim 123, wherein the dose is approximately a 10 g dose delivering 50 mg to about 100 mg of testosterone to the skin.

127. (New) The method of claim 123, wherein the composition is provided to the subject in one or more packets.

128. (New) The method of claim 127, wherein the packet comprises a polyethylene liner between the composition and inner surface of the packet.

129. (New) The method of claim 104, wherein maximum serum testosterone concentration in the subject is reached about 16 hours after the application of the composition on day one of administration.

130. (New) The method of claim 104, wherein after at least about 30 days of daily application serum testosterone concentration in the subject is about 490 ng/dl to about 860 ng/dl.

131. (New) The method of claim 104, wherein after at least about 30 days of daily application serum dihydrotestosterone concentration in the subject is greater than about 54 ng/dl.

132. (New) The method of claim 104, wherein after at least about 30 days of daily application a ratio of serum dihydrotestosterone concentration to serum testosterone concentration of greater than about 0.23 is achieved in the subject.

133. (New) The method of claim 104, wherein after at least about 30 days of daily application total serum androgen concentration in the subject is greater than about 372 ng/dl.

134. (New) The method of claim 104, wherein after at least about 30 days of daily application serum estradiol concentration in the subject is greater than about 28 pg/ml.

135. (New) The method of claim 104, wherein the subject has primary hypogonadism prior to application.

136. (New) The method of claim 135, wherein after at least about 30 days of daily application serum follicle stimulating hormone concentration in the subject is less than about 11 mIU/ml.

137. (New) The method of claim 104, wherein the subject has secondary hypogonadism prior to application.

138. (New) The method of claim 137, wherein after at least about 30 days of daily application serum follicle stimulating hormone concentration in the subject is less than about 3.7 mIU/ml.

139. (New) The method of claim 104, wherein the subject has a pretreatment serum follicle stimulating hormone concentration greater than normal range of a normal subject.

140. (New) The method of claim 139, wherein after at least about 30 days of daily application the serum follicle stimulating hormone concentration is within or below the normal range.

141. (New) The method of claim 104, wherein the subject has a pretreatment serum luteinizing hormone concentration greater than a normal range of a subject having primary hypogonadal.

142. (New) The method of claim 141, wherein after at least about 30 days of daily application serum luteinizing hormone concentration is within the normal range.

143. (New) The method of claim 141, wherein after at least about 30 days of daily application the serum luteinizing hormone concentration is less than about 6.8 mlU/ml.

144. (New) The method of claim 104, wherein after at least about 30 days of daily application the testosterone has an accumulation ratio in the male subject greater than about 1.5.

145. (New) The method of claim 104, wherein after at least about 30 days of daily application the testosterone has a net AUC_{0-24} in the male subject greater than 220 nmol*h/l.